JUL 2 8 2009

510(k) SUMMARY

Pursuant to 510(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and in accordance with 21 CFR § 807.92.

Submitter Information:

Medicel AG
Contact: Volker Dockhorn
Chief Operating Officer
Luchten 1262
Wolfhalden CH 9427
Switzerland
Phone: 41-71-727-1057
Fax: 41-71-727-1055

FDA Registration Number: 9681862

Submission Correspondent:

Medicel AG
Contact: Volker Dockhorn
(Official Correspondent)

Medsys Inc.
Contact: Dr. George Myers
President
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Phone: 201-727-1703 Fax: 201-727-1708

Date Summary Prepared: February 20, 2009

Classification Name: Folders and Injectors, Intraocular Lens (IOL) (Class I) – MSS 21 CFR 886.4300

Common/Usual Name: Intraocular Lens Guide

Device Trade Name: Navject™ Sub2-1P IOL Injector Set

Equivalent legally-marketed devices: K070669, IOL Intraocular Injector Set, Medicel AG

1. Intended Use:

The Navijet Sub2-1P IOL Injector and Cartridge Set for intraocular lenses is indicated for the insertion only of models of intraocular lenses that allow use of this injector.in their approved labeling.

2. Description:

The Navijet Sub2-1P IOL Injector and Cartridge Set is a sterile, single-use device intended to fold and insert a STAAR Surgical Visian ICL phakic intraocular lens through surgical procedure in a human eye. The system provides a tubular pathway through an incision over the iris, allowing delivery of an IOL into the human eye.

3. Technological Characteristics:

The Navijet Sub2-1P IOL Injector Set has substantially equivalent technological characteristics to the predicate devices. Refer to **Table 1** in the following section, entitled *Comparison Analysis*, for a summation of technological characteristics such as design, dimensional specifications, and material.

4. Comparison Analysis:

The overall design of the Navijet Sub2-1P IOL Injector Set is substantially equivalent to the predicate device. See **Table 1** for a comparison of the new Navijet Sub2-1P IOL Injector Set and the predicate device.

Feature	Navject Sub2-1P IOL Injector Set	K070669	Substantially Equivalent
Product Description	This Injector and Cartridge Set is a sterile, single-use device intended to fold and insert a STAAR Surgical Visian ICL phakic intraocular lens through surgical procedure in a human eye. The system provides a tubular pathway through an incision over the iris, allowing delivery of an IOL into the human eye.	Same, except for use with different IOLs	Yes
Intended Use	The Navject Sub2-1P IOL Injector and Cartridge Set for intraocular lenses is indicated for the insertion only of models of intraocular lenses that allow use of this injector in their approved labeling.	Same, except for use with different IOLs	Yes
Design	This device has 3 basic components: a syringe type injector with a silicone cushion tip plunger, a 33° bevel down cartridge tip and a loading block.	Same, except for the 40° bevel up cartridge tip	Yes
Materials	Plastic materials: ABS, Polydimethilsiloxane (Silicone) and Polypropylene with GMS additive	Same	Yes
Mechanical Safety	Validated for STAAR Surgical phakic Visian ICL intraocular lenses	Same, except with different IOLs	Yes
Manufacturing	Per internal operating procedures	Same	Yes
Operating Principle	An IOL is loaded into the cartridge, then pushed through the cartridge and delivered into a human eye through a 2.2 mm surgical incision.	Same	Yes
Packaging	Labeled blister trays with Tyvek material lids and boxes	Same	Yes
Sterility	Sterile (EO)	Same	Yes
Manufacturer	Medicel AG	Medicel AG	Yes

Table 1: Summary of Design Comparison

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medicel AG
c/o George Myers, M.D
377 Route 17 South
Hasbrouck Heights, NJ 07604

JUL 2 8 2009

Re: K092023
Trade/Device Name: Naviject™ Sub2-1P IOL Injector Set
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: April 3, 2009
Received: July 6, 2009

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092023

Device Name: Naviject™ Sub2-1P IOL Injector Set

Indications For Use:

The Naviject Sub2-1P IOL Injector and Cartridge Set for intraocular lenses is indicated for the insertion only of models of intraocular lenses that allow use of this injector in their approved labeling.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092023